

STUDY 2

TOP SELLING NON-PATENTED SINGLE SOURCE DRUG PRODUCTS, 1996:

INTERNATIONAL PRICE COMPARISON

**Federal/Provincial/Territorial
Task Force on Pharmaceutical Prices**

April, 1999

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June 17 -18, 1999, Charlottetown, P.E.I.

EXECUTIVE SUMMARY

- This study reports on an international comparison of factory gate prices of Canada's top selling non-patented single source (NPSS) prescription drugs.
- In the study, Canadian prices of these top selling NPSS drugs were compared to their prices in the seven countries used by the Patented Medicine Prices Review (PMPRB) to regulate patented medicines: France; Germany; Italy; Sweden; Switzerland; the United Kingdom; and the United States.
- The study found that Canadian prices for these top selling NPSS drug products were, on average, substantially higher (30%) than the median international price of the seven countries. These findings are based on comparisons of manufacturers' prices in the seven countries with manufacturers' prices in Canada.
- This analysis suggests that had these medicines been priced at median international levels, spending by the six provincial drug plans would have been about \$64 million less than the \$278 million these plans spent on NPSS drug products in 1996.
- Top selling NPSS drug products measured in this study were identified from the top 50 selling NPSS drug products in both the Ontario Drug Benefit and the British Columbia Pharmacare data bases. From these data bases, a total of 72 drug products were used across six provincial drug plans for purposes of conducting this study.
- In 1996 these 72 top selling NPSS drugs comprised 10% of total pharmaceutical expenditures in Canada.
- NPSS drug products account for an important share to total drug sales. In 1996 manufacturer's sales of all NPSS drug products were \$1.6 billion; this represents approximately 24% of total expenditures of pharmaceuticals in Canada.

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TOP SELLING NON-PATENTED SINGLE SOURCE DRUG PRODUCTS, 1996 INTERNATIONAL PRICE COMPARISON

1.0 INTRODUCTION

In March, 1997, the Federal Provincial Territorial (F/P/T) Task Force on Pharmaceutical Prices prepared an overview paper which provided a description of the pharmaceutical sector in Canada, a summary of existing information on drug prices and spending, as well as mechanisms used by private and public payers for regulating and/or influencing pharmaceutical prices. From this research, it was concluded that more detailed analyses of such prices and expenditures were needed. It was noted, that further research should be undertaken not only at an aggregate level, but also according to key criteria including, for example, whether a product is available from one or several competing sources; and whether or not a medicine is patented.

The Task Force has since examined price and expenditure trends, price levels, and cost drivers as they relate to prescription drugs reimbursed under six provincial drug plans.¹ The first of these analyses measured how prices and spending have changed between 1990 and 1997. Subsequent studies have assessed prices of non-breakthrough patented drugs; single source non-patented drugs; and multiple source non-patented (generic) drugs; an inter-provincial price comparison study was also undertaken. Finally, the Task Force has developed and applied a "cost-driver" analysis that has accurately measured the role of changes in existing drug prices, changes in utilization, and the impact of newly introduced medicines to changes in total drug spending.

The contribution of this Paper is to gain a better understanding of non-patented single source drug price behaviour, as well as report on an International comparison of Canada's top selling non-patented single source prescription drugs in 1996.

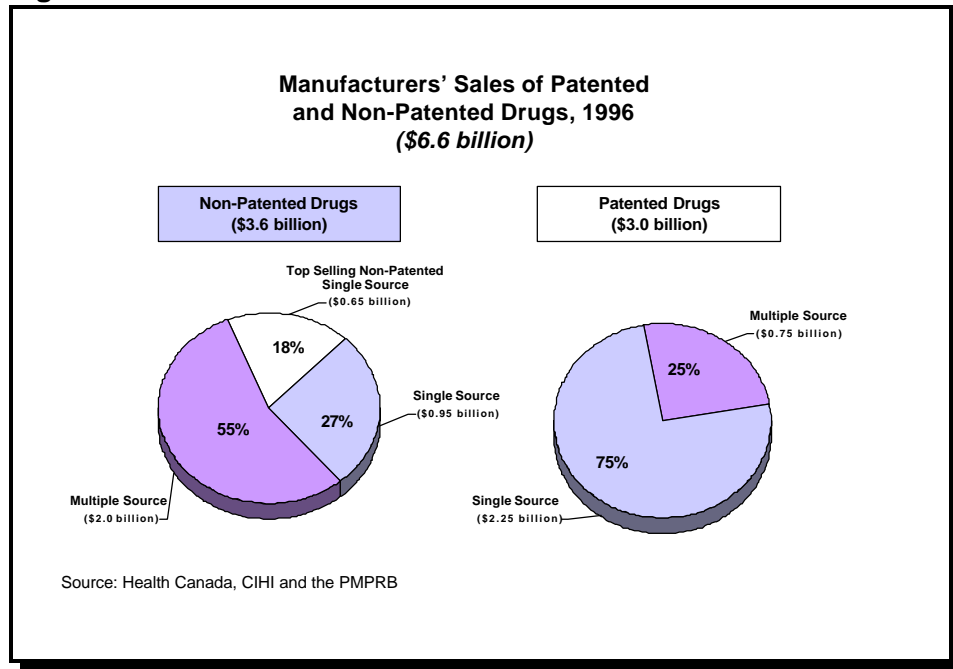
¹ The Task Force has representatives from British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia, Health Canada and the Patented Medicine Prices Review Board. It was established to examine one of six pharmaceutical issues identified at the April 1996 meeting of federal/provincial/territorial Ministers of Health. The other issues included utilization, marketing, wastage, consumer education and research and development. The work is overseen by the Pharmaceutical Issues Committee (PIC) of the Advisory Committee on Health Services (ACHS), which reports to the Conference of Deputy Ministers of Health.

1.1 Focus of Report

To gain a better understanding of the current price level for non-patented single source drugs in Canada, this study reports on international price comparisons, at the factory gate, of the top selling non-patented single source prescription drug products with the seven countries used by the Patented Medicine Prices Review Board (PMPRB) for purposes of patented drugs.^{2 3}

As shown in Figure 1, in 1996, total manufacturers' sales of non-patented single source (NPSS) drug products was approximately \$1.6 billion. This represents about 24% of the total expenditures of pharmaceuticals in Canada. The NPSS drugs, analyzed in this report, comprise about 41% of the total expenditures for NPSS drugs, or 10% of total pharmaceutical expenditures in Canada. These drugs tend to be "older" products, with an average market life of 17 years.⁴

Figure 1



² The seven countries listed in the *Patented Medicines Regulations* include France, Germany, Italy, Sweden, Switzerland, U.K. and U.S. International price comparisons for non-patented single source drugs products were conducted using the same methodology the PMPRB employs for patented drug products.

³ See PMPRB (1998) *Tenth Annual Report, for the year ended December 31, 1997, Ottawa: PMPRB*. That analysis demonstrated that Canadian prices of patented drug products were, on average, 11% below the median international prices of the seven foreign countries.

⁴ See IMS (1997) *Canadian Pharmaceutical Industry Review*.

2.0 METHODOLOGY

International price comparisons of the top selling NPSS drug products were performed for 1996. The top selling NPSS drugs were identified from the top 50 selling NPSS drugs in both the Ontario Drug Benefit and the British Columbia Pharmacare data bases. From these data bases, a total of 72 drug products were used across six provincial drug plans for purposes of conducting this study.

Non-patented drugs include those drug products that were never patented, were previously patented, or whose patents have been dedicated. Single source drug products are defined as drugs containing a unique chemical, strength, dosage form and route of administration and sold by one manufacturer. It is important to note that some single source drugs examined in this study, have subsequently become multiple source drugs.⁵ Appendix 1 provides the complete list of drug products included in this study along with the year of introduction and their sales in 1996.⁶

To determine if drugs were patented or non-patented, the PMPRB data base was used to group drugs according to patent status.

2.1 Price Information

Prices of the 72 NPSS drug products were obtained from the Ontario Drug Benefit (ODB) formulary, if available. For drug products not listed on the ODB, prices were obtained from the British Columbia Pharmacare data base. All prices were compared at the manufacturers ex-factory level, i.e., excluding wholesale and/or retail mark-ups where applicable.

Prices for the seven comparator countries were obtained from public sources (see Appendix 2) available in each country. Manufacturers' prices were calculated by "backing out" the manufacturers' ex-factory prices from the retail prices published by the official sources.⁷ The publicly available prices in most countries do not include dispensing fees, general pharmacy and dispensary fees and Value Added Taxes (VAT). Adjustments were made when necessary to ensure that prices in all countries were comparable i.e., the manufacturers' ex-factory prices were based on an "apples to apples" comparison.

⁵ These medicines include; Aventyl, Depakene, Betagan, Imuran, Ponstan, Buspar, Restoril, Euflex, Tryptan, Adnrocur, Isoptin and Imovane. The 1996 sales of these products totalled approximately \$125 million or approximately 21% of the \$600 million of the top 72 selling non-patented source drugs.

⁶ Sales are based on sales reported by IMS Canada.

⁷ Ex-factory prices were calculated after adjusting for retail and wholesale mark ups, as well as, value added taxes, when applicable. These mark-ups are legislated in most countries. See the PMPRB's (1998) "*Verification of Foreign Patented Drug Prices*" for a description of how ex-factory prices are derived in six of the seven countries (excluding the United States).

Since all drug products were not sold in all countries, the number of drug products varied across countries. Sweden had the least number of drugs at 32, the United States and the United Kingdom had the highest number of drugs at 55 each, Germany had 53 drugs, Switzerland had 50 drugs, Italy had 46 and France had 45 drug products.

3.0 ANALYSIS

The analysis illustrated that Canadian prices for non-patented single source drug products were, on average, substantially higher than the median international price of the seven countries. The overall ratio of Canadian prices to median international prices was 1.30.⁸ In other words, Canadian prices for non-patented single source drugs were, on average, 30% higher than the median international price. Table 1 provides a summary of the instances where Canadian prices were the highest, lowest and above the median of the foreign prices. In most cases, 53 out of 72 or 73.6%, Canadian drugs were priced above the median international price. The number of cases where the Canadian price was the highest was 14 (19.4%). Canadian prices were the lowest of all countries in six (8.3%) instances.

Table 1

Top Selling Non-patented Single Source Drug Products, 1996 International Price Comparison		
Total # of Drug Products	72	
	#	%
Canadian Price Highest	14	19.4
Canadian Price Lowest	6	8.3
Canadian Price Below Median International Price	19	26.4
Canadian Price Above Median International Price	53	73.6
Canadian Price/Median International Price	1.3	

⁸ The average Canadian to foreign price ratios in this study are based on the geometric mean.

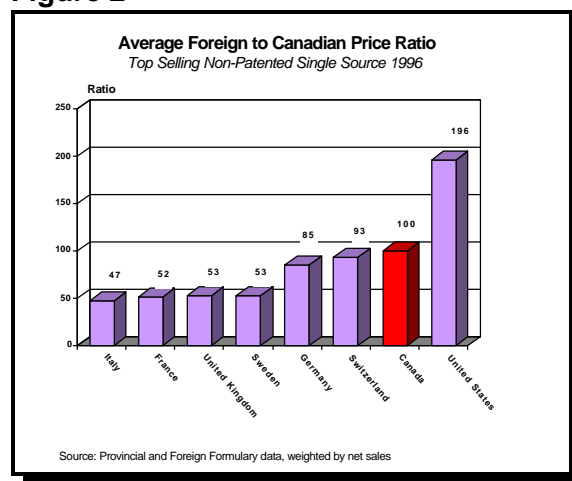
Table 2 compares Canadian prices to each of the foreign countries. It shows the frequency of cases where the Canadian prices were below the price in the foreign country, as well as the average ratio of Canadian prices to foreign prices for the year 1996. As shown in the Table, Canadian prices were, on average, below those in the United States but higher than in the remaining countries.

Table 2

Top Selling Non-Patented Single Source Drug Products by Country, 1996: Foreign to Canadian Price Ratios				
Comparison Country	# of Drugs	Canada price below foreign price		Average Price Ratio (Cdn/ Foreign)
		#	%	
France	45	5	11.1	1.92
Germany	53	17	32.1	1.18
Italy	46	8	17.4	2.14
Sweden	32	7	21.9	1.89
Switzerland	50	23	46	1.08
U.K.	55	7	12.7	1.9
U.S.A.	55	51	92.7	0.51

The data in Table 2 can also be used to show how the level of prices of Canadian non-patented single source drug products compared with the seven countries. Figure 2 is based on the information in Table 2. Setting Canadian prices at 100, the range of foreign prices varied from 47 to 196. In other words, prices in Italy were, on average, 47% of Canadian prices, while prices in the United States were, on average, 96% higher than Canadian prices. Overall, Canada ranked second behind the United States.

Figure 2



3.1 Comparison of International Prices of Non-Patented Drugs and Patented Drugs

The PMPRB has published analyses of international price comparisons for the top selling patented drugs since 1992. In the first international price comparison for the top selling patented drug prices, it was found that Canadians were often paying more for patented drug products than citizens in most other reference countries. The exception was the United States.

Effective in 1994, the PMPRB amended its Guidelines to put greater emphasis on international price comparisons for new and existing drugs, with the objective that prices, on average, should not exceed median international prices.

As shown in Figure 2, the relationship of Canadian prices of non-patented single source drugs to foreign prices in 1996 was similar to the relationship of patented prices to foreign prices in 1987 presented in Figure 3. At that time Canada ranked second and was higher priced than the remaining countries. In 1997, Canada ranked sixth, behind all countries with the exception of France and Italy (Figure 4).

Figure 3

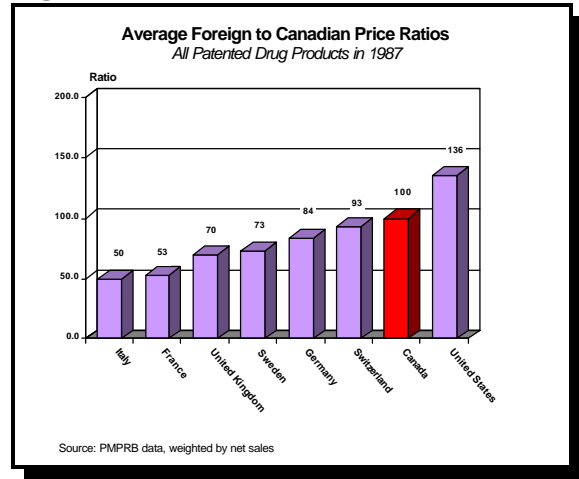
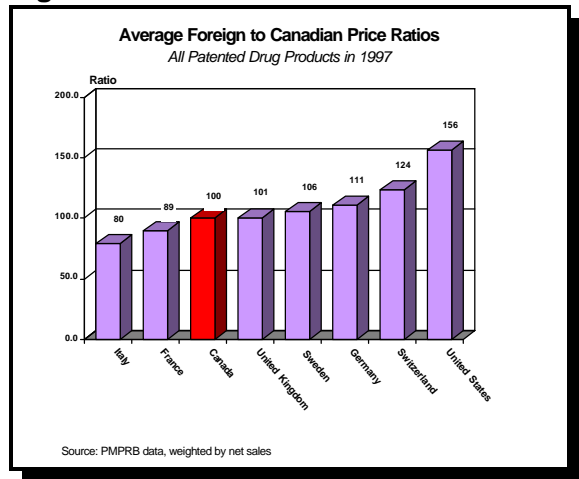


Figure 4



4.0 CONCLUSIONS

The findings demonstrate that Canadian prices of top selling non-patented single source drugs are significantly higher than prices in the seven countries listed in the *Patented Medicines Regulations*. These findings are based on comparisons of manufacturers' prices in the seven countries with manufacturers' prices in Canada.

This analysis suggests that had these medicines been priced at median international level, spending by the six provincial drug plans would have been reduced by 23% (\$64 million less than the \$278 million these plans spent on NPSS drug products in 1996). This represents approximately 3% of drug plan spending in that year.

APPENDIX 1

LIST OF DRUGS

DIN	Trade Name	Company	Year of Introduction	Sales 1996 (\$'s)
582352	Accutane CAP 40 mg	Roche	1983	14,925,000
704431⁹	Androcur TAB 50 mg	Berlex Canada	1987	22,851,000
579327	Asasantine CAP	Boehringer Ingelheim	1983	737,000
576158	Atrovent AEM 28.6 mg/100GM	Boehringer Ingelheim	1983	-
15237	Aventyl Pulvule 389 25 mg	Lilly	1965	4,343,000
897353	Becloforte 250 mcg/AEM	Glaxo	1988	77,885,000
637661	Betagan 0.5% Ophthalmic SOL	Allergan	1985	6,842,000
249580	Biquin Durules 250 mg	Astra	1972	2,138,000
1981501	Botox PWS Inj 100 Unit/Vial	Allergan	1991	3,975,000
603821	Buspar Tab 10 mg	Bristol	1989	6,249,000
2097265	Cardizem CD CAP 240 mg	Merrell Dow Pharm.	1992	51,460,000
2212277	Ceftin TAB 250 mg	Glaxo Wellcome	1990	9,586,000
2212285	Ceftin TAB 500 mg	Glaxo Wellcome	1990	7,674,000
265470	CES Tab .625 mg	ICN Canada	1963	3,993,000
894745	Clozaril Tab 100 mg	Sandoz	1991	16,143,000
894737	Clozaril Tab 25 mg	Sandoz	1991	1,683,000
1918311	Coumadin Tab 1mg	Du Pont Pharma	1990	4,262,000
1918338	Coumadin Tab 2 mg	Du Pont Pharma	1956	6,993,000
1918346	Coumadin Tab2.5 mg	Du Pont Pharma	1956	4,445,000

⁹ All drugs that appear in bold are no longer non-patented single source drug products since 1996.

DIN	Trade Name	Company	Year of Introduction	Sales 1996 (\$'s)
1918354	Coumadin Tab 5 mg	Du Pont Pharma	1956	8,413,000
632600	Cytotec Tab 200 mcg	Searle	1986	15,193,000
30570	Dalacin C Capsules 150 mg	Upjohn	1970	6,097,000
261432	Darvon N 100 mg Pulvule 392	Lilly	1973	1,016,000
507989	Depakene Cap 500 mg	Abbott	1991	3,145,000
765996	Diamicon Tab 80 mg	Servier Lab	1990	7,525,000
1950592	Dicetel Tab 50 mg	Solvay Kingswood	1994	2,197,000
22780	Dilantin Cap 100 mg	Parke-Davis	1951	5,690,000
846368	Ergamisol Tab 50 mg	Janssen Pharm	1990	2,277,000
637726	Euflex Tab 250 mg	Schering	1985	12,983,000
586668	Fucidin Cream 2%	Leo	1980	5,208,000
465283	Hydrea Cap 500 mg	Squibb	1981	3,755,000
1926799	Imovane Tab 7.5 mg	Rhone-Poulenc Rorer	1990	14,260,000
4596	Imuran Tab 50 mg	B.W. Inc.	1966	9,313,000
1934317	Isoptin SR Tab 180 mg	Searle	1993	1,780,000
1907223	Isoptin SR Tab 120 mg	Searle	1992	1,959,000
742554	Isoptin SR Tab 240 mg	Searle	1988	25,470,000
35319	Lanoxin Tab .125 mg	B.W. Inc.	1972	5,637,000
2170027	Loxapac TAB 5 mg	Wyeth-Ayerst	1976	1,612,000
2170132	Loxapac TAB 10 mg	Wyeth-Ayerst	1976	1,274,000
2170019	Loxapac TAB 25 mg	Wyeth-Ayerst	1976	1,497,000
2170698	Methotrexate Tab 2.5 mg	Wyeth-Ayerst	1995	351,000
2126567	Monistat Derm Cr. Top 2%	McNeil Consumer	1975	775,000
2042339	Min-Ovral 28 Tab	Wyeth-Ayerst	1974	1,933,000
2015439	MS Contin SRT 15 mg	Purdue Frederick	1986	3,895,000
2014327	MS Contin SRT 200 mg	Purdue Frederick	1993	3,047,000

DIN	Trade Name	Company	Year of Introduction	Sales 1996 (\$'s)
1913328	Nasacort Liq 100 mcg/AEM	Rhone-Poulenc Rorer	1992	3,460,000
772368	Nix Creme Rinse	Warnaer-Lambert	1988	1,994,000
1926721	Nitrolingual Spray 0.4mg/AEM	Rhone-Poulenc Rorer	1986	7,803,000
1927809	Nitrong SR Tab 2.6 mg	Rhone-Poulenc Rorer	1966	13,150,000
1966154	Norflex Tab 100mg	3M Pharmaceuticals	1960	3,943,000
766046	Ocufen OPH Soln .03%	Allergan Inc.	1988	1,031,000
568643	Parlodol CAP 5 mg	Sandoz	1983	3,768,000
769991	PCE Tab 333mg	Abbott Lab	1988	2,896,000
2017709	Plaquenil Tab 200 mg	Sanofi Winthrop	1952	5,957,000
449628	Ponderal PACAPS 60 mg	Servier	1979	6,455,000
155225	Ponstan Cap 250 mg	Parke-Davis	1966	3,667,000
529117	Propine LIQ .1%	Allergan Inc.	1981	1,790,000
604453	Restoril Cap 15 mg	Sandoz	1981	3,497,000
604461	Restoril Cap 30 mg	Sandoz	1981	4,779,000
603708	Rythmol Tab 150 mg	Knoll	1987	7,854,000
603726	Rythmol Tab 300 mg	Knoll	1988	2,793,000
846341	Sibelum Cap 5mg	Janssen	1990	3,858,000
2103567	Sulcrate suspension Plus-1g/5ml	Merrell Dow	1991	3,744,000
1966065	Tantum LIQ .15%	3M Pharmaceuticals	1982	5,172,000
773611	Tegretol CR Tab 200 mg	Geigy	1988	6,361,000
755583	Tegretol CR Tab 400 mg	Geigy	1988	7,720,000
654531	Tryptan Tab 1000 mg	ICN	1986	3,941,000
728179	Urispas Tab 200 mg	Pharmascience	1986	3,536,000
1945254	Ursofalk Cap 250 mg	Jouveinal	1991	2,490,000

DIN	Trade Name	Company	Year of Introduction	Sales 1996 (\$'s)
2014165	UniphyI SRT 400 mg	Purdue Frederick	1987	2,235,000
616192	Vepesid Cap 50 mg	Bristol Labs	1981	4,165,000
577308	Zaditen Tab 1 mg	Sandoz	1990	1,728,000

Legend

AEM - aerosol
 Cap - capsule
 C - cream
 Inj - injectable
 Liq - liquid
 Oph - ophthalmic
 PWS - powder for solution
 Sol - solution
 SRT - sustained-release tablet
 Tab - tablet

APPENDIX 2

PRICING STRUCTURES

France: SEMPEX

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